Whole blood

Section: 11. Blood products, coagulation factors, and plasma substitutes > 11.1. Blood and blood components

EMLc | ATC codes: Pending

Indication	Blood transfusion without reported diagnosis ICD11 code: QB98
Medicine type	Biological agent
List type	Core
Additional notes	In accordance with the World Health Assembly resolution WHA63.12, WHO recognizes that achieving self-sufficiency, unless special circumstances preclude it, in the supply of safe blood components based on voluntary, non-remunerated blood donation, and the security of that supply are important national goals to prevent blood shortages and meet the transfusion requirements of the patient population. All preparations should comply with the WHO requirements.
Formulations	**Parenteral > General injections > IV:**
EML status history	First added in 2013 (TRS 985)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Read more about patents.
Tags	Biological
Wikipedia	Whole blood

Summary of evidence and Expert Committee recommendations

An application was submitted by AABB (formerly the American Association of Blood Banks), the American Red Cross and Canadian Blood Services for the inclusion of whole blood and red blood cells in the EML. Extensive comments were received from ministries of health, medicines and blood regulatory authorities, multilateral agencies, experts in transfusion medicine and their professional associations, Red Cross national societies, patient organizations and associations of voluntary blood donors. All comments remain available on the WHO EML website at: http://www.who.int/selection_medicines/committees/expert/19/applications/blood. The application stated that the inclusion of whole blood and red blood cells in the EML would accomplish several critical objectives in furtherance of World Health Assembly resolution WHA63.12 on the availability, safety and quality of blood products. These would include: ■ heightened awareness of the need for blood in every country and of the role of blood in protecting public health; ■ government responsibility for ensuring sustainable funding and support for a safe and adequate supply of blood that is accessible to patients in need; ■ creation of a favourable environment for governments for national regulation dealing with blood and blood products; ■ investment in infrastructure, systems and governance for blood establishments; ■ additional emphasis on the need for effective and efficient procurement systems to provide equipment, supplies and reagents to collect, process, test, store and transport blood; ■ additional emphasis on the need to ensure that blood is cost-effective, affordable and available; and ■ enabling, and putting additional emphasis on the importance of, appropriate regulatory oversight of blood collection, processing, testing, storage and distribution to ensure the safety and quality of blood and the safety of blood transfusion. The Expert Committee noted the discussion in the Open Session which reflected the many

comments received and made available on the WHO EML website, both supporting and opposing the inclusion of whole blood and red blood cells in the EML. The Committee considered the fact that the application raised many issues that span technical, clinical, ethical and regulatory issues. The Expert Committee discussed whether blood could be considered as a “medicine”, since this was a key issue highlighted in many of the comments both for and against inclusion. While noting that blood may be different from conventional medicines in that it is a “human-derived biological material”, it was acknowledged that many countries already regulate blood as a “biological medicine”. The heading of Section 11 in the first EML of 1977 was “Blood and haematopoietic system drugs”. It was also noted that the WHO Expert Committee on Biological Standardization defines blood products as “any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products”. The Committee agreed that there was no need to debate whether blood and red blood cells were essential as they were necessary for the treatment and management of many clinical conditions – such as anaemia and diseases of the blood (where the haemoglobin levels requiring transfusion are well defined), gastrointestinal bleeding and injuries – as well as during surgery, and for obstetric conditions such as postpartum haemorrhage and neonatal conditions requiring exchange transfusions (1-6). The Expert Committee also considered the issue of safety of blood. On the basis of the application and the comments, the safety issues relating to the use of blood were well defined and the importance of appropriate quality standards for its production were clear. Global application of these standards would improve the safety of blood for use in transfusion. It was noted that the risk of transfusion-mediated viral infections remains a constant concern. The Expert Committee discussed the cost of delivering appropriate quality blood products. The cost of production is recognized as significant but WHO has taken many steps over the years to support countries in developing affordable and high-quality transfusion services. The Committee recognized the need to promote the appropriate use of transfusion to ensure that its cost–effectiveness would be maintained. The Expert Committee further considered the concerns raised by some Member States and organizations regarding payment for donors, commercialization and commodification, including arguments relating to factor VIII and factor IX complex that are currently in the EML. Factors VIII and IX are supplied as commercial products, are used for a very limited number of conditions affecting a small population, and require sophisticated manufacturing technology; therefore they cannot be seen as examples of commodification for whole blood or red blood cells which have a limited lifespan/shelf-life and are used in very different clinical situations that affect a much larger population. The Committee noted that neither the applicant nor any of the comments provided data to support the claims that listing blood and red blood cells in the EML would lead to their commodification. It was noted that medicines regulatory authorities, through the ICDRA resolution,5 had expressed a strong preference for listing blood and red blood cells as an essential medicine to advance access to safe blood products that are appropriately regulated and traceable. Listing as an essential medicine would not be a sufficient solution in itself but would enable the beginning of a systematic approach to improving access to safe blood products. The Expert Committee noted that World Health Assembly resolution WHA63.12 called on Member States “to enhance the quality of evaluation and regulatory actions in the area of blood products and associated medical devices, including in vitro diagnostic devices”. The Committee fully concurred that listing whole blood and red blood cells in the EML would not be contradictory to the principles of voluntary, nonremunerated blood donation, as noted in World Health Assembly resolution WHA63.12. Such a listing would strongly support these principles. Having considered all the above arguments, the Expert Committee decided to change the heading of Section 11 to “Blood products of human origin and plasma substitutes” and to restructure the section to specify blood products clearly. The note under Subsection 11.2 would be moved to Subsection 11.1 and would be updated to reflect World Health Assembly resolution WHA63.12. Subsection 11.1 would be relabelled “Blood and blood components” and would list fresh–frozen plasma, red blood cells, platelets and whole blood. The balance of the section would be renumbered. Subsection 11.2 would be labelled “Plasma-derived medicinal products”, with a Subsection 11.2.1 labelled “Human immunoglobulins”. Subsection 11.2.2 would be labelled “Blood coagulation factors” and would list factor VIII and factor IX. Subsection 11.3 would be labelled “Plasma substitutes”. A note would also be inserted to indicate that a review of this last subsection would be needed at the next meeting of the Expert Committee as the subsection contains dextran, and that the Committee should also consider a possible move of the three immunoglobulins (anti-D, anti-tetanus and anti-rabies) from Section 19.2 to the new Subsection 11.2.1.

References: 1. English M, Ahmed M, Ngando C, Berkley J, Ross A. Blood transfusion for severe anaemia in children

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